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Food and Drug Administration  
Rockville MD 20857

MAY - 9 1995

Re: Zosyn®  
Docket No. 94E-0071

Stephen G. Kunin  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, DC 20231

RECEIVED  
MAY 15 1995  
OFFICE OF THE ASSISTANT  
COMMISSIONER FOR PATENTS

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 4,562,073 filed by Taiho Pharmaceutical Company, Ltd. under 35 U.S.C. § 156. The patent claims the human drug product Zosyn®, New Drug Application (NDA) 50-684.

In the August 30, 1994 issue of the Federal Register (59 Fed. Reg. 44,738), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before February 27, 1995, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. The beginning of the testing phase was corrected in the April 24, 1995 issue of a Federal Register (60 Fed. Reg. 20,107) and the regulatory review period recalculated. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson  
Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: Richard J. Berman  
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Washington, D.C. 20005-5701